# SPECIAL 510(k): Device Modification

To: THE FILE RE: DOCUMENT NUMBER K051218

UniCAP® Specific IgE Assay and UniCAP® Specific IgE Conjugate 100 and 400

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: UniCAP® Specific IgE Assay (k962274)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED *(page 1 of 16 under the section "General Information")*** along with the proposed labeling which includes instructions for use, package labeling.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   **This change was for:**

   - a change in the calibrator system in order to extend the technical measuring range for specific IgE antibodies below 0.35 $kU_A/l$;
   - The change includes addition of a 0 kU/l calibrator and removal of the 50 kU/l calibrator, keeping the same number of calibrators in the kit;
   - change in LOD from <0.35 $kU_A/l$ to 0.1 $kU_A/l$; and
   - change in calibrator reagent name from UniCAP Specific IgE Calibrators to ImmunoCAP Specific IgE Calibrators 0-100
4. **Comparison Information** (similarities and differences): The differences to applicant's legally marketed predicate device are listed in #3. The similarities to applicant's legally marketed predicate device are in labeling, intended use, sample type, antibody, method principle, instrumentation, sample volume, incubation temperature and process time.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis ***(page 7 of 16 and Report on Risk Analysis).***
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied ***(page 7 of 16 and Report on Risk Analysis).***
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met ***(page 12 of 16)***, and

ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review ***(page 12 of 16)***.

**6.** A **Truthful and Accurate Statement**, a **510(k) Summary** and the **Indications for Use Enclosure.**

The labeling for the modified subject devices has been reviewed to verify that the indication/intended use statements for the devices are unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the devices be determined substantially equivalent to the previously cleared devices.